REMARKS

Claims 13-16 and 26-31 were pending in the application. Claim 13 has been amended and claims 14-16 and 26-31 have been canceled. Accordingly, upon entry of the amendments presented herein, claim 13 will remain pending in the application.

Claim 13 has been amended to specify a method for diagnosing a gluten sensitive enteropathic autoimmune disease consisting of dermatitis herpetiformis and coeliac disease, comprising (a) taking a sample from a patient; (b) testing the sample for IgA antibodies against human tissue transglutaminase; (c) testing the sample for IgA antibodies against epidermal transglutaminase (TGe) and (d) correlating significantly increased amounts of the IgA antibodies specific for human tissue transglutaminase and IgA antibodies specific for TGe as compared to a control sample, with a diagnosis of a gluten sensitive enteropathic autoimmune disease, thereby diagnosing a gluten sensitive enteropathic autoimmune disease. Support for this amendment can be found throughout the specification and claims as originally filed. Specifically, support is available at page 13, line 19 through page 15, line 16 and the claims as originally filed.

No new matter has been added. Any amendment and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was performed solely in the interest of expediting prosecution of the application. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Further, no additional search is required and no new issues have been raised by the amendments made herein; support for the amendments made can be found in the specification as filed and/or in the claims as previously pending. Furthermore, in view of the amendments and arguments set forth herein, the number of issues for appeal have been reduced and it is believed that the Examiner's rejections under §112, first paragraph has been obviated by the present claim amendments and cancellations. Therefore, the claim amendments and cancellations made herein are permissible under 37 C.F.R. §1.116 as reducing the number of issues for appeal, and Applicants respectfully request that the present Amendment be entered.

Acknowledgment of the Examiner's Withdrawal of Certain Rejections

Applicants acknowledge with appreciation the withdrawal of the prior rejection of claims 13 and 14 under 35 U.S.C. § 102(b) or (e) as being anticipate by Schuppan *et al.* (WO 98/03873 or US 6,319,726).

Rejection of Claims 13 and 14Under 35 U.S.C. § 112, First Paragraph - Enablement

The Examiner has rejected claims 13 and 14 under 35 U.S.C. § 112, First Paragraph, as lacking enablement because, according to the Examiner,

> the specification, while being enabling for diagnosing gluten sensitive enteropathic autoimmune disease consisting of dermatitis herpetiformis and coeliac disease by testing a sample from a patient for IgA antibodies directed against human tissue transglutaminase and testing the sample for IgA antibodies directed against epidermal transglutaminase (TGe) and correlating significantly increased amounts of the IgA antibodies specific for human tissue transglutaminase and IgA antibodies specific for epidermal transglutaminase, does not reasonably provide enablement for any and all gluten sensitive enteropathic autoimmune diseases or another transglutaminase such as FXIIIA, transglutaminase X (TGx) and Band 4.2 or by correlating only a single result to a diagnosis.

Applicants respectfully traverse the foregoing rejection. However, to expedite prosecution and allowance of the pending claims, Applicants have canceled claim 14 and amended claim 13 to specify the particular embodiment that the Examiner has deemed enabled. Specifically, claim 13, as amended is drawn to a method for diagnosing a gluten sensitive enteropathic autoimmune disease consisting of dermatitis herpetiformis and coeliac disease, comprising (a) taking a sample from a patient; (b) testing the sample for IgA antibodies against human tissue transglutaminase; (c) testing the sample for IgA antibodies against epidermal transglutaminase (TGe) and (d) correlating significantly increased amounts of the IgA antibodies specific for human tissue transglutaminase and IgA antibodies specific for TGe as compared to a control sample, with a diagnosis of a gluten sensitive enteropathic autoimmune disease, thereby diagnosing a gluten sensitive enteropathic autoimmune disease. Further, as confirmed by the enclosed publications by Hull CM *et al.*, *Br J Dermatol.* 2008 Jul; 159(1):120-4 (enclosed herewith as Appendix A), Marietta *et al.*, *J Invest Dermatol.* 2008 Feb;128(2):332-5 (enclosed herewith as Appendix B), Rose, *J. Am. Acad. Dermatol.* 2009 Jul;61(1):39-43 (enclosed

herewith as Appendix C), Sardy *et al.*, *J Exp Med.* 2002 Mar 18;195(6):747) (enclosed herewith as Appendix D), and Donaldson MR *et al.*, *J. Invest. Dermatol.* 2007 May; 127(5):1268-71 (enclosed herewith as Appendix E), it is clear that that the presently claimed methods can indeed be used for diagnosing dermatitis dermatitis herpetiformis and coeliac disease.

In view of the foregoing, Applicants respectfully request that that the Examiner reconsider and withdraw the foregoing rejection.

CONCLUSION

In view of the above amendments and remarks set forth above, it is respectfully submitted that this application is in condition for allowance. If there are any remaining issues or the Examiner believes that a telephone conversation with Applicants' Attorney could be helpful in expediting prosecution of this application, the Examiner is invited to call the undersigned at (617) 227-7400.

Dated: December 8, 2009

Respectfully submitted,
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